

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

**IN RE PHARMACEUTICAL
INDUSTRY AVERAGE WHOLESALE
PRICE LITIGATION**

MDL NO. 1456

CIVIL ACTION: 01-CV-12257-PBS

**THIS DOCUMENT RELATES TO 01-
CV-12257-PBS and 01-CV-339**

Judge Patti B. Saris

**Chief Magistrate Judge
Marianne B. Bowler**

**TRACK ONE DEFENDANTS' MEMORANDUM IN OPPOSITION TO
PLAINTIFFS' MOTION TO STRIKE
PORTIONS OF THE DECLARATION OF ROBERT P. NAVARRO**

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The Track 1 Defendants submit this Memorandum in Response to Plaintiffs' Motion to Strike portions of the Declaration of Robert P. Navarro. For the reasons set forth below, Plaintiffs' motion should be denied in its entirety.

PRELIMINARY STATEMENT

Plaintiffs' claim that the Declaration of Robert P. Navarro in Opposition to the Plaintiffs' Motion for Class Certification is (1) irrelevant to the Court's decision on class certification in this case, and (2) biased and unreliable. Neither of these assertions has merit.

First, Plaintiffs' misunderstand and misconstrue the nature of Dr. Navarro's testimony. Dr. Navarro is not being offered as a legal expert on class certification issues or as an economic expert. Rather, his testimony is offered to assist the Court in understanding the role of the Pharmacy Benefit Manager ("PBM") in the pharmaceutical reimbursement system, and to support Defendants' arguments that pharmaceutical reimbursement is not based upon form contracts but rather a web of proprietary contracts that are negotiated individually and competitively among manufacturers, wholesalers, pharmacies, PBMs and third-party payors. Based upon his extensive experience in the PBM industry, Dr. Navarro is uniquely qualified to testify about the pharmaceutical reimbursement system and the role of PBMs in that system. Dr. Navarro is also uniquely qualified to opine that the reimbursement analysis cannot be understood without a detailed review of each negotiated contract and the highly complex and individualized contract terms. Dr. Navarro has the expertise to assist the Court in understanding these issues.

Second, Dr. Navarro's Declaration should not be stricken, as Plaintiffs suggest, on the basis that he is not "independent" or "credible." Dr. Navarro's prior consultation for pharmaceutical companies does not render his opinions inadmissible. Nor is there any merit to Plaintiffs' claim that portions of Dr. Navarro's Declaration do not reflect his own opinions and

were instead written by Defendants' attorneys. The complete record demonstrates unequivocally that Dr. Navarro's opinions are based upon his own independent analysis. Defendants' attorneys provided only secretarial assistance and the legal scaffolding necessary to enable Dr. Navarro – who is not a lawyer – to address the relevant issues. Such assistance is not only permissible, it is often well advised, and has been routinely endorsed by courts. Indeed, plaintiffs adopted the same approach with at least one of their experts.

For these reasons, Plaintiffs' Motion to Strike should be denied.

ARGUMENT

I. DR. NAVARRO'S DECLARATION IS RELEVANT TO THE COURT'S DECISION WHETHER TO GRANT PLAINTIFFS' MOTION FOR CLASS CERTIFICATION

A. Dr. Navarro is Offered as an Expert on the PBM Industry and Not as a Legal or Economic Expert

Plaintiffs admit that Dr. Navarro is qualified to provide "observations regarding PBM practices," because he has "approximately twenty (20) years of experience in managed care pharmacy practice." As a result, they are left to argue that Defendants somehow seek "to use Mr. Navarro in ways far beyond his qualifications and expertise." See Class Plaintiffs' Memorandum in Support of Their Motion to Strike Portions of the Declaration of Robert P. Navarro ("Plaintiffs' Memo") at 2, 5. Defendants are attempting no such thing. Plaintiffs simply misconstrue and misunderstand the nature of Dr. Navarro's testimony.

Plaintiffs assert that Dr. Navarro is "not qualified to provide opinion testimony as to whether class impact and/or damages may be established by common proof and. . . to provide observations as to whether allegations of the AMCC are consistent with Defendants' and PBMs' profit-making motives." See id. at 2. Plaintiffs also object that Dr. Navarro has not testified

concerning class certification before and that he is not an economist. Id. at 7. Both of these facts are irrelevant and have no bearing on Dr. Navarro's qualifications to serve as a PBM expert here.

First, the fact that Dr. Navarro has limited experience as an expert witness does not make him unqualified; experts do not materialize from thin air. See Plywood Property Assocs., v. Nat'l Flood Ins. Program, 928 F. Supp. 500, 508 (D.N.J. 1996) (explaining that "[p]rior qualification as an expert witness" is "not required to be possessed by every witness acting as an expert"). See also Daubert v. Merrell Dow Pharma., Inc., 43 F.3d 1311, 1317 (9th Cir. 1995) ("[I]n determining whether proposed expert testimony amounts to good science, we may not ignore the fact that a scientist's normal workplace is the lab or the field, not the courtroom or the lawyer's office."). It is expertise that matters, not experience as a testifying witness. See Thomas J. Kline, Inc. v. Lorillard, Inc., 878 F.2d 791, 800 (4th Cir. 1989) ("Although it would be incorrect to conclude that [a witness's] occupation as a professional expert alone requires exclusion of her testimony, it would be absurd to conclude that one can become an expert simply by accumulating experience in testifying.").

Second, Defendants are not offering Dr. Navarro as an economist—Dr. Eric Gaier is being offered for that purpose. Nor must Dr. Navarro be an economist in order to serve as an expert here. Federal Rule of Evidence 702 provides that a witness may be "qualified as an expert by *knowledge, skill, experience, training, or education*" (emphasis added); the rule thus "expressly contemplates that an expert may be qualified on the basis of experience. . . ." Id., Advisory Comm. Notes, 2000 Amendment; see, also, Kumho Tire Co. v. Carmichael, 526 U.S. 137, 156 (1999) ("[N]o one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience."); Tokio Marine & Fire Ins. Co. v. Grove Mfg. Co., 958 F.2d 1169, 1175 (1st Cir. 1992) (explaining that "Rule 702 does not require

specific educational training in the area of expertise"); United States v. Paiva, 892 F.2d 148, 160 (1st Cir. 1989) ("A witness may qualify as an expert on any one of [Rule 702's] five listed grounds."). In addition, an expert may be offered to assist the Court in understanding background facts concerning a particular industry or business. See, e.g., First Nat'l State Bank of New Jersey v. Reliance Electric Co., 668 F.2d 725, 731 (3rd Cir. 1981) (holding that courts have "wide discretion" to determine the admissibility of expert testimony and allowing expert testimony on banking customs and industry practices). For this reason, Plaintiffs' suggestion that the issues raised in the Declaration are those which "do not require an expert's opinion," Plaintiffs' Brief, at 5, is baseless. As discussed more fully below, Dr. Navarro has the experience necessary to serve as a PBM expert in this case, and that expertise will aid the Court's determination on class certification.

B. Dr. Navarro is Uniquely Qualified to Address PBM Issues

Dr. Navarro's Declaration, and his curriculum vitae attached to the Declaration as Appendix A, describe his education, experience and expertise in detail. (Navarro Decl., ¶¶ 3-9). Dr. Navarro was educated as a clinical pharmacist and spent over 15 years working for three major health plans and two major PBMs. Id., at ¶ 3. Dr. Navarro was involved in developing and managing three managed pharmacy benefit programs. Id., at ¶ 6. He also has extensive knowledge of the PBM selection, bidding and negotiation process and the development of drug formularies. Id., at ¶ 7. Finally, he has experience and knowledge of PBM negotiations with pharmacies and with drug manufacturers. Id., at ¶ 8-9. As Plaintiffs readily admit, Dr. Navarro "has experience in managed care and has worked for a pharmacy benefit manager"¹ and is

¹ In fact, he has worked for two.

"arguably qualified to provide some observations regarding PBM practices." Plaintiffs' Brief, at 2. Despite this, Plaintiffs somehow claim that Dr. Navarro is insufficiently qualified.

Dr. Navarro's experience is more than adequate to establish that he can assist the Court in understanding the role of the PBM in the pharmaceutical reimbursement system. It is well-settled that "the rejection of expert testimony is the exception rather than the rule." Fed. R. Evid. 702, Advisory Comm. Notes, 2000 Amendment. As indicated throughout his Declaration, Dr. Navarro has extensive experience and expertise concerning the role of the PBM in the pharmaceutical reimbursement process. In addition, Dr. Navarro reviewed numerous PBM contracts and deposition transcripts produced in discovery in this case and relied upon a smaller group to complete his Declaration. (Navarro Dep., at 80-81, 88)². Defendants are not seeking "to use Mr. Navarro in ways far beyond his qualifications and expertise."

C. All of the Points Raised in Dr. Navarro's Declaration are Relevant to the Class Certification Issues Before the Court

Plaintiffs object to any portion of the Declaration containing opinions that somehow concern: (i) whether class impact or damages can be established through common proof, (ii) the differences in non-price aspects of PBM transactions, (iii) whether allegations in the Complaint are consistent with the practices of the four main PBMs, and (iv) collective knowledge of the meaning of AWP in the industry.³

The two major themes of Dr. Navarro's Declaration are (i) that "the role of the PBM varies" significantly depending on the identity, objectives and leverage of the parties to

² Plaintiffs have provided citations to the rough transcript of Dr. Navarro's deposition, taken on November 17, 2004. Defendants citations herein are to the final version of Dr. Navarro's deposition transcript, which was provided to the Court as Plaintiffs' Exhibit 6.

³ Throughout their brief, Plaintiffs do not specifically indicate which sections of the Declaration they find objectionable. Nor do Plaintiffs provide much of an explanation for why the Declaration is irrelevant, spending only one and a half pages on relevance and devoting the bulk of their brief to unfairly attacking Dr. Navarro's independence and credibility.

those contracts" and (ii) that "[t]his variability means that any understanding of the reimbursement analysis requires a detailed review of each negotiated contract and the highly complex and individualized contract terms." (Navarro Declaration, ¶ 2.) This testimony is relevant to class certification because it demonstrates the individualized nature of the contracting process and the individualized factual determinations that would be needed if a class were certified.⁴ This distinguishes the putative class members in this case from those in securities or consumer fraud cases "premised on uniform contract terms or sales pitches that are not subject to negotiation." See Defendants' Brief in Opposition to Class Certification ("Def. Brief"), at 29.

The formulation of legal conclusions arising from the facts discussed in Dr. Navarro's Declaration, and how those conclusions affect Plaintiffs' Motion for Class Certification, is the job of the Court, not Dr. Navarro. Nowhere in his Declaration does Dr. Navarro attempt to opine upon the legal or economic conclusions to be drawn from his opinions.

Plaintiffs effort to strike portions of the Declaration concerning the differences in non-price aspects of the PBM transactions is also meritless. In Part VII of his Declaration, entitled "Variability in PBM Contracting," Dr. Navarro discusses such differences: "The relationships between PBMs and its [sic] customers, pharmacies and manufactures are defined by contracts that vary widely depending on the objectives and the relative leverage of the parties. The process by which the terms are negotiated also varies. . . ." (Navarro Decl., ¶ 57). Dr. Navarro's opinions on this subject, based upon his years of experience in the industry, are relevant to the issues now before the Court. As stated in Defendants' brief:

⁴ Plaintiffs assert that this variability is "immaterial." Plaintiffs' Brief, at 6. To the contrary, as Dr. Navarro stated in his Declaration, PBM contracts "vary widely" and "are based upon a competitive bidding process." (Navarro Decl., ¶¶ 57, 59).

The multi-faceted nature of these relationships between third-party payors and PBMs is significant because the contractual relationships ultimately negotiated by payors and PBMs/physicians embody a number of considerations unique to the particular payor, as well as numerous factors other than AWP that potentially influence the payor's decision. As a result, isolating a casual link between a single aspect of the contractual relationship—e.g., drug reimbursement formula—and defendants' alleged conduct is difficult and contractually specific.

Def. Brief, at 31. The implication that Dr. Navarro is himself drawing legal conclusions concerning class certification from these opinions is unfounded. Dr. Navarro is merely describing the facts, based upon his expertise. Legal conclusions are for the Court.

Third, Plaintiffs assert, without any explanation, that the Declaration addresses "whether certain allegations made in the AMCC are consistent with PBM practices of the four major PBMs" and that Dr. Navarro's opinions on this subject are irrelevant. Plaintiffs' Brief, at 2. First, the majority of Dr. Navarro's Declaration does not concern the specific allegations in the AMCC, but rather his knowledge of the PBM industry. Second, based on this experience and knowledge, Dr. Navarro is qualified to rebut the factual basis for Plaintiffs' claims. See Navarro Decl., ¶ 40 (stating that Plaintiffs' claim that "PBMs routinely substitute higher cost drugs for those on formulary in order to earn rebates from manufacturers. . . would not be tolerated by the PBMS' customers"). Third, Dr. Navarro's testimony is not limited to a discussion of the practices of four major PBMs. As evidenced by the two volumes of materials submitted as exhibits to the Declaration, Dr. Navarro reviewed and analyzed testimony and contracts of many smaller PBMs in addition to the major four. Finally, Dr. Navarro does not draw legal conclusions from his experience, and a determination of whether the allegations in the AMCC are consistent with PBM practices across the industry, as established through discovery in this case and through Dr. Navarro's past experience, is a matter left to Court.

Finally, Plaintiffs object to Dr. Navarro's opinions regarding the industry's collective knowledge of the meaning of AWP. Part VI of Dr. Navarro's Declaration discusses "the use of pricing benchmarks." Dr. Navarro is qualified to give these opinions based upon his years of experience in the industry and his review of documents obtained by the parties in discovery.⁵ Dr. Navarro testified that pricing benchmarks are used because they are "a convenient means of analyzing the relative value of proposed reimbursement to PBMs or pharmacies." Navarro Decl., ¶ 45.

This testimony supports Defendants' theory that AWP is used because it is convenient. As argued in Defendants' brief, "[c]ontrary to plaintiffs' allegations, discovery has shown that a number of major third-party payors in the proposed class did not use AWP as a way to approximate acquisition costs." Defendants' Brief, at 32. Rather, as Dr. Navarro testified in his Declaration, AWP was used as a benchmark to allow third party payors to process "millions of transactions that must be reimbursed every day." Navarro Decl., ¶ 46; see also Defendants' Brief, at 33.

II. DR. NAVARRO'S OPINIONS ARE INDEPENDENT AND CREDIBLE

A. Dr. Navarro is Independent and There is No Basis to Strike his Declaration of the Grounds of his Prior Industry Experience

Plaintiffs assert that Dr. Navarro's Declaration should be "disregarded because of his lack of independence" because he has "worked in the pharmaceutical industry for his entire career and has frequently served as a consultant to pharmaceutical manufacturers." Plaintiffs' Brief, at 7. This claim is absurd. First, any lack of "independence" goes not to admissibility of expert testimony, but to its appropriate weight. See Den Norske Bank, A.S. v. First Nat'l Bank of

⁵ As discussed below, Plaintiffs' objection that Dr. Navarro's opinions are purportedly inconsistent with earlier opinions simply goes to the weight of his testimony.

Boston, 75 F.3d 49, 58 (1st Cir. 1996) (court not persuaded that "the expert qualifications of these affiants are undermined by their present and former association with [the plaintiff] so as to render their testimony inadmissible. Of course, such matters may bear heavily on witness credibility, bias, and the weight of the evidence. But these matters are for the factfinder."). In addition, under Plaintiffs' rubric, no one could possibly serve as an expert on the role of PBMs in the pharmaceutical reimbursement system because, according to Plaintiffs, a lifetime of work with PBMs and pharmaceutical companies is proof of "bias." To the contrary, Dr. Navarro's lifetime experiences in the industry make him uniquely qualified to submit his Declaration.

B. Dr. Navarro Prepared and Authored his Declaration

Defendants also seek to strike portions of Dr. Navarro's Declaration on the grounds that he "permitted Defendants' counsel to prepare the first draft of his Declaration " and contend that "it is impossible to tell how much of the report has been drafted by Mr. Navarro, and how much has been shaped by defense lawyers." See Plaintiffs' Memo, at 7-8. These claims lack foundation in law or fact.

The record demonstrates that Dr. Navarro expended considerable time and effort creating and revising his Declaration. Dr. Navarro provided input for an outline before a draft report was even prepared. (Navarro Dep., at 89). He had telephone calls and then a preliminary meeting with Defendants' counsel. Id. He then asked Defendants' counsel to "reduce some of the discussions that we had to writing, in sort of an organized manner." Id. Dr. Navarro substantially reworked that outline, a process that eventually resulted in a preliminary draft.

There was a subsequent meeting. I think we looked at that. I took that home, and I made a lot of suggestions, and basically re – reworded – it wasn't a draft at that point. It was just a brief document. Reorganized it, and as a result of some subsequent conversations, I asked [defendants' counsel] to put a few more

words in there and provide sort of a very preliminary draft based upon the discussions that we had and my recommendations.

Navarro Dep. at 89-90. Even the draft memorializing Dr. Navarro's views was a mere starting point, and Dr. Navarro revised his Declaration several times thereafter. Id. at 90.

Notably, plaintiffs adopted the same approach with their own expert, Stephen Schondelmeyer. As Dr. Schondelmeyer testified at his deposition, plaintiffs' counsel prepared the first draft of his report (Schondelmeyer Dep., at 20):

Q. Who prepared the initial draft of this document?

A. This document was initiated first with a discussion between myself and Plaintiffs' counsel, and I asked if they could reduce that discussion to a document. And then thereafter, I took responsibility for all additions and changes in the document.

Authorship of expert reports is governed by Federal Rule of Civil Procedure 26(a)(2)(B), which requires disclosure to the opposing party of a written report "prepared and signed by" the testifying expert. However, it is clear from the 1993 Advisory Committee Notes that Rule 26(a)(2)(B) was not intended to exclude attorneys from the report drafting process:

Rule 26(a)(2)(B) does not preclude counsel from providing assistance to experts in preparing the reports.... Nevertheless, the report, which is intended to set forth the substance of the direct examination, should be written in a manner that reflects the testimony to be given by the witness and it must be signed by the witness.

See 1993 Advisory Comm. Notes to Rule 26, cited in Marek v. Moore, 171 F.R.D. 298, 301 (D. Kan. 1997); see also Nexxus Products Co. v. CVS New York, Inc., 188 F.R.D. 7, 11 (D. Mass. 1999) (citing Advisory Comm. Notes for proposition that "[c]ounsel are not precluded from assisting experts in preparing the expert reports").

In line with this flexible and practical approach, courts have routinely rejected motions to strike expert reports or testimony on the grounds that counsel helped to prepare

reports. See, e.g., Gallardo v. Reineccius, No. CV-F. 97-6111, 1998 U.S. Dist. LEXIS 18484, at *6-8 (E.D. Cal. Nov. 18, 1998) ("[t]he fact that counsels' staff typed the reports is irrelevant" and "absent conclusive proof that someone other than the expert prepared the report, courts should not strike a party's expert"); ISOM v. Howmedica, Inc., No. 00C5872, 2002 WL 1052030, at *1 (N.D. Ill. May 22, 2002) ("reject[ing] a formalistic approach which would require that the expert be the person who actually puts pen to paper (or fingers to keyboard)"); Indiana Ins. Co. v. Hussey Seating Co., 176 F.R.D. 291 (S.D. Ind. 1997) (motion to strike dismissed because expert had been involved in the process and had prepared sections of the report). Not only is assistance of counsel in preparing an expert report permissible, it is often desirable:

Unlike the attorney, the expert witness more likely preoccupies himself with his profession or field of expertise. He may have little appreciation or none whatsoever for Rule 26 and its exacting requirements for a legally "complete" report of the expert opinions, including all the "data and other information" and designating all supporting exhibits.... To help ensure complete disclosure of the required information, counsel ordinarily should supervise preparation of the expert's written report.

Marek, 171 F.R.D. at 301 (quoting William W. Schwarzer et al., *Civil Discovery & Mandatory Disclosure: A Guide to Efficient Practice* § 1[B][3] (2d ed. 1994)). Thus, Defense counsel assistance to Dr. Navarro in preparing his Declaration provides no basis to strike Dr. Navarro's Declaration.

C. Plaintiffs Fail to Offer Any Other Evidence that the Declaration is Not Credible

Plaintiffs suggest that Dr. Navarro's Declaration is not credible because his understanding of AWP as expressed in his Declaration is somehow inconsistent with his prior opinions concerning AWP. Plaintiffs rely upon a glossary definition in a textbook that Dr. Navarro edited and a portion of an essay written by a contributor of another textbook which lists

Dr. Navarro as an editor. Plaintiffs' Brief, at 8-9. Plaintiffs charge that Dr. Navarro nefariously "sought to avoid all responsibility" for the statements in these textbooks. Id., at 9.

However, plaintiffs have offered nothing to refute Dr. Navarro's statement that he was not the author of either statement. He testified that the glossary definition was "supplied by the publisher" without his input (Navarro Dep., 117) and that the essay was written by a contributor in an edition of a textbook that Dr. Navarro "had nothing to do with." (Navarro Dep., at 157). In any event, although Dr. Navarro testified that he did not agree with the glossary definition or the portion of the essay, neither contradicts his opinions in his Declaration concerning the use of pricing benchmarks.

In summary, Plaintiffs have failed to show that Dr. Navarro's testimony is "fatally flawed" or otherwise lacks credibility sufficient to strike portions of his Declaration. Plaintiffs had the opportunity to cross examine Dr. Navarro during his deposition. Plaintiffs objections to Dr. Navarro's testimony go towards his credibility, if anything, and certainly not towards the admissibility of his Declaration.

CONCLUSION

For the reasons stated above, Plaintiffs Motion to Strike Portions of the Declaration of Robert P. Navarro should be denied in its entirety.

Respectfully submitted,

THE TRACK 1 DEFENDANTS

By: /s/ Jessica V. Barnett

Nicholas C. Theodorou (BBO # 496730)
Jessica V. Barnett (BBO # 650535)
FOLEY HOAG LLP
155 Seaport Boulevard
Boston, MA 02110

D. Scott Wise
Michael Flynn
Kimberley Harris
DAVIS POLK & WARDWELL
450 Lexington Avenue
New York, NY 10017

Attorneys for AstraZeneca Pharmaceuticals LP

Steven M. Edwards
Lyndon M. Tretter
Hogan & Hartson, LLP
875 Third Avenue
New York, NY 10022

Attorneys for the Bristol-Myers Squibb Co.,
Oncology
Therapeutics Network Corp., and Apothecon, Inc.

Mark H. Lynch
COVINGTON & BURLING
1201 Pennsylvania Avenue, N.W.
Washington, DC 20004-7566

Frederick G. Herold
DECHERT LLP
975 Page Mill Road
Palo Alto, CA 94304-1013

Geoffrey E. Hobart
HOLLAND & KNIGHT LLP
10 St. James Ave.
Boston, MA 02116

Attorneys for SmithKlineBeecham Corp.
d/b/a GlaxoSmithKline

William F. Cavanaugh, Jr.
Andrew D. Schau
Erik Haas
PATTERSON, BELKNAP, WEBB & TYLER LLP
1133 Avenue of the Americas
New York, NY 10036 6710

Attorneys for the Johnson and Johnson Defendants

John T. Montgomery
Brien T. O'Connor
Steven A. Kaufman
Darcy W. Shearer
Eric P. Christofferson
ROPES & GRAY LLP
One International Place
Boston, MA 02110

Attorneys for Schering-Plough Corp. and
Warrick Pharmaceuticals Corp.

Dated: January 21, 2005

CERTIFICATE OF SERVICE

I hereby certify that on January 21, 2005, I caused a true and correct copy of Track One Defendants' Memorandum in Opposition to Plaintiffs' Motion to Strike Portions of the Declaration of Robert P. Navarro to be served on all counsel of record by electronic service pursuant to Case Management Order No. 2.

/s/ Jessica V. Barnett
Jessica V. Barnett